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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,211

01/04/2006

Axel Ullrich

2923-743

6030

6449

7590

05/18/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

05/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,211	ULLRICH ET AL.	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9 and 13-33 is/are pending in the application.
- 4a) Of the above claim(s) 28-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9, 13-27 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed on 3/3/09 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 2-9,13-27 and 30-33 are examined on the merits and claims 28-29 remain withdrawn as being drawn to a non-elected invention.

The rejection of claims 2,15-18,22,26,27, and 30-33 under 35 U.S.C. 102(e) as being anticipated by Uckun *et al* (US Patent 6,864,286) is withdrawn in view of applicant's arguments.

The rejection of claims 2-5,15-18,22,26-27, and 30-33 under 35 U.S.C. 102(e) as being anticipated by Agus (US Patent 7,384,940) is withdrawn in view of applicant's arguments.

The rejection of claims 2,15-17,23-25, and 30-33 under 35 U.S.C. 102(e) as being anticipated by Majumdar (US Patent 6,582,934) in view of applicant's arguments.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 2-9,13-27,30, and 33 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a hyperproliferative cells in vitro comprising the administration of an inhibitor of a receptor tyrosine kinase ligand (such as a nucleic acid inhibitors, proteins, antibodies, and low

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molecular weight compounds), does not reasonably provide enablement for a method of treating or preventing a hyperproliferative disease in vivo comprising the administration of an inhibitor of a receptor tyrosine kinase ligand. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons for this rejection are of record in the paper mailed 9/5/08.

Applicant argues that the reference chosen by the Examiner are no longer relevant because of the rapidly advancing field of vaccines. While the field is rapidly advancing, applicant has not provided any objective evidence to show that in vitro assays are readily correlatable by one skilled in the art. In the absence of objective evidence to show this correlation, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2,15-18,22,26-27 and 30-33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tang *et al* (US Patent 5,773,459). The reasons for this rejection are of record in the paper mailed 9/5/08.

Applicant argues that the inhibitor of the reference is not directed to inhibiting the ligand. As disclosed in col. 19-20, the ELISA assay shows that the drug inhibits the binding of the ligand to the receptor (see steps IIIA-E in col. 20). Thus, the drug is inhibiting the ligand.

Claims 2,6,8-9,15-19,22,26-27, and 30-33 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US Patent 6,537,988).). The reasons for this rejection are of record in the paper mailed 9/5/08.

Applicant argues that the inhibitor of the reference is not directed to inhibiting the ligand. As disclosed in col. 10, lines 30-35 examples of antiproliferative agents include epidermal growth factor inhibitors. The epidermal growth factor reads on the ligand and thus the reference discloses ligand inhibitors.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday-Thursday 6am to 2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/
Primary Examiner
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